JUN 18 2007

510(k) SUMMARY of Safety and Effectiveness K070288

(In accordance with SMDA of 1990 and pursuant with 21 CFR 807.92)

I. Applicant Information:

Date Prepared:	January 29, 2007
Submitter:	Medtronic, Inc.
Address:	710 Medtronic Parkway, NE Minneapolis, MN 55432-5604
Establishment Registration No.	2135394
Contact Person:	Debbie Kidder. Senior Regulatory Affairs Specialist
Telephone Number:	(763) 391-9251
Fax Number:	(763) 391-9279

II. Device Information:

Trade Name:	Cardioblate® Monopolar Pen, Model 60813 and XL Pen Model 60814
Common Name:	Cardioblate® Surgical Ablation System, which consists of the Cardioblate® Surgical Ablation Generator (K060400) and Monopolar Pen (K013392 and K031247)
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification:	Class II, 21 CFR 878.4400
Product Code:	GEI
Device Description:	The Medtronic Cardioblate® Monopolar Pen is a hand-held, electrosurgical instrument intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy when connected to the Cardioblate® 68000 generator along with a return electrode when the operator presses the footswitch. In addition, the Cardioblate Pen can be used with the Medtronic Model 2090/2290 Programmer/Analyzer, and the Medtronic Model 5348/5388 External Temporary Pacemaker. When connected to a ground

source, the monopolar pen can sense depolarization's of the ventricle and stimulate (pace) either the atrium or ventricle. The Cardioblate Pen is intended for intermittent operation, is sterile, non-pyrogenic, disposable, and single use only.

Intended Use: The Cardioblate® Monopolar Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® generator or for temporary cardiac pacing, sensing, recording and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker.

Contraindications: The Medtronic Cardioblate® System is contraindicated for patients that have active endocarditis at the time of surgery.

Predicate Device 1: Medtronic Detect™ Surgical Pacing and Mapping Tool
510(k) No. K040812, Reg. No. 870.3680; Product Code: LDF

Predicate Device Intended Use: The Medtronic Detect™ Surgical Pacing and Mapping Tool is a handheld, single use device designed to provide temporary cardiac pacing or monitoring.

Predicate Device 2: Atricure Isolator™ Transpolar Pen System
510(k) No. K061593, Reg. No. 878.4400; Product Code: GEI

Predicate Device Intended Use: The Isolator™ Transpolar Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissues during cardiac surgery using radiofrequency energy when connected to the Atricure Ablation and Sensing Unit or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

Predicate Device 3: Medtronic Cardioblate® Monopolar Pen
510(k) No. K013392 and K031247, Reg. No. 878.4400;
Product Code: GEI

Predicate Device Intended Use: The Cardioblate® device is currently indicated to ablate cardiac tissue during general surgery using radiofrequency energy.

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III. SUBSTANTIAL EQUIVALENCE SUMMARY

The Cardioblate Monopolar Pen Model 60813 and XL Pen Model 60814 are equivalent to the predicate products in their indications for use, basic overall function and materials. The performance characteristics of the Cardioblate Monopolar Pen and XL Pen were tested and compared to the performance specification of the Detect Surgical Pacing and Mapping Tool. There have been no changes to the Cardioblate Monopolar Pen that is currently marketed today in order to expand the indication for use. The Cardioblate® Monopolar Pens, Model 60813 and XL Pen Model 60814 have been tested and are considered safe and effective per the following standards for Medical Electrical Equipment: Part 1:General Requirements, IEC 60601-1 and, IEC 60601-2-27

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2008

Medtronic, Inc.
c/o Mr. Scott Cundy
Senior Director Regulatory and Clinical
Medtronic Cardiac Surgery
7601 Northland Drive
Minneapolis, MN 55428

Re: K070288
Trade/Device Name: Cardioblate Monopolar Pen model 60813 and
Cardioblate XL Monopolar Pen model 60814
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II (two)
Product Code: OCL
Dated: May 30, 2007

Dear Mr. Cundy:

This letter corrects our substantially equivalent letter of June 18, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

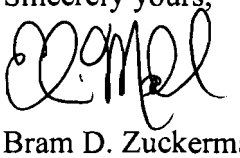
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K070288

Device Name: Medtronic Cardioblate® Surgical Ablation Pen and XL Pen (Models 60813 and 60814)

Indications for use:

The Cardioblate® Monopolar Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® generator or for temporary cardiac pacing, sensing, recording and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker.

Prescription Use ___x___ **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070288